(2) *Indications for use.* Administer to dogs, cats, and horses to stimulate respiration during and after general anesthesia; or to speed awakening and return of reflexes after anesthesia. Administer to neonate dogs and cats to initiate respiration following dystocia or caesarean section; or to stimulate respiration following dystocia or caesarean section.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 261, Jan. 4, 2007, as amended at 75 FR 10167, Mar. 5, 2010; 77 FR 60302, Oct. 3, 2012]

§ 522.784 Doxylamine.

(a) *Specifications.* Each milliliter contains 11.36 milligrams (mg) of doxylamine succinate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Horses:* Administer 25 mg per hundred pounds of body weight by intramuscular, subcutaneous, or slow intravenous injection.

(ii) *Dogs and cats:* Administer 0.5 to 1 mg per pound of body weight by intramuscular or subcutaneous injection. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect.

(2) *Indications for use.* For use in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16187, Mar. 25, 2014]

§ 522.800 Droperidol and fentanyl.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) of droperidol and 0.4 mg of fentanyl citrate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.*

(i) For analgesia and tranquilization, administer as follows:

(A) 1 milliliter (mL) per 15 to 20 pounds (lbs) of body weight by intramuscular injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight; or

(B) 1 mL per 25 to 60 lbs of body weight by intravenous injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight.

(ii) For general anesthesia, administer as follows:

(A) Administer 1 mL per 40 lbs of body weight by intramuscular injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight and followed in 10 minutes by an intravenous administration of sodium pentobarbital at the rate of 3 mg per pound of body weight; or

(B) Administer 1 mL per 25 to 60 lbs of body weight by intravenous injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight and followed within 15 seconds by an intravenous administration of sodium pentobarbital at the rate of 3 mg per pound of body weight.

(2) *Indications for use.* As an analgesic and tranquilizer and for general anesthesia.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16187, Mar. 25, 2014]

§ 522.810 Embutramide, chloroquine, and lidocaine solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 135 milligrams (mg) embutramide; 45 mg chloroquine phosphate, U.S.P.; and 1.9 mg lidocaine, U.S.P.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* One mL per 5 pounds of body weight.

(2) *Indications for use.* For euthanasia.

(3) *Limitations.* Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 36337, June 23, 2005, as amended at 78 FR 17597, Mar. 22, 2013]

§ 522.812 Enrofloxacin.

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 22.7 milligrams (mg) enrofloxacin or

(2) 100 mg enrofloxacin.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter:

(1) No. 000859 for use of products described in paragraph (a) as in paragraph (e) of this section; and

(2) No. 055529 for use of product described in paragraph (a)(2) as in paragraphs (e)(2)(i)(B), (e)(2)(ii)(B), (e)(2)(iii), (e)(3)(i), and (e)(3)(iii) of this section.

(c) *Related tolerance.* See § 556.226 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

(e) *Conditions of use*—(1) *Dogs.* Use the product described in paragraph (a)(1) of this section as follows:

(i) *Amount.* 2.5 mg per kilogram (/kg) of body weight (1.13 mg per pound) as a single, intramuscular, initial dose followed by use of tablets twice daily for 2 to 3 days beyond cessation of clinical signs to a maximum of 10 days.

(ii) *Indications for use.* For the management of diseases associated with bacteria susceptible to enrofloxacin.

(2) *Cattle.* Use the product described in paragraph (a)(2) of this section as follows:

(i) *Amount*—(A) *Single-dose therapy:* For treatment of bovine respiratory disease (BRD), administer 7.5 to 12.5 mg/kg of body weight (3.4 to 5.7 mL per 100 pounds (/100 lb)) once by subcutaneous injection. For control of BRD, administer 7.5 mg/kg of body weight (3.4 mL/100 lb) once by subcutaneous injection.

(B) *Multiple-day therapy:* For treatment of BRD, administer 2.5 to 5.0 mg/kg of body weight (1.1 to 2.3 mL/100 lb) by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 3 days. Additional treatments may be given on days 4 and 5 to animals that have shown clinical improvement but not total recovery.

(ii) *Indications for use*—(A) *Single-dose therapy:* For the treatment of BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* in beef and nonlactating dairy cattle; for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni* and *M. bovis.*

(B) *Multiple-day therapy:* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef and non-lactating dairy cattle.

(iii) *Limitations.* Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. This product is not approved for female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Swine.* Use the product described in paragraph (a)(2) of this section as follows:

(i) *Amount.* Administer 7.5 mg/kg of body weight once, by subcutaneous injection behind the ear.

(ii) *Indications for use*—(A) For the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, *Streptococcus suis*, *Bordetella bronchiseptica*, and *Mycoplasma hyopneumoniae.*

(B) For the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis.*

(iii) *Limitations.* Animals intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose.

[72 FR 10597, Mar. 9, 2007, as amended at 73 FR 17890, Apr. 2, 2008; 73 FR 21819, Apr. 23, 2008; 76 FR 22611, Apr. 22, 2011; 77 FR 55415, Sept. 10, 2012; 77 FR 76863, Dec. 31, 2012; 78 FR 19987, Apr. 3, 2013]

§ 522.814 Eprinomectin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) eprinomectin.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.